NOV 3 0 2001

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K012521

Submitter:
Binax, Inc.
217 Read Street
Portland, Maine 04103
(207) 772-3988 (Office)
(207) 871-5751 (FAX)

Contact Person:
Pamela S. Angell
pangell@binax.com (email)

Trade Name:
Binax NOW® *Streptococcus pneumoniae* Test

Common Name:
Strep pneumo ICT, Binax NOW® *Strep pneumo* test

Classification Name:
Streptococcus spp. serological reagents (per 21 CFR 8660.3740)

Predicate Device:
Wellcogen Bacterial Antigen Kit, 510(k) number K854852

Device Description:
The Binax NOW® *Streptococcus pneumoniae* Test is an immunochromatographic membrane assay used to detect pneumococcal soluble antigen in human urine and CSF. Rabbit anti-*S.* pneumoniae antibody, the Sample Line, is adsorbed onto nictrocellulose membrane. Control antibody is adsorbed onto the same membrane as a second stripe. Both rabbit anti-*S. pneumoniae* and anti-species antibodies are conjugated to visualizing particles that are dried onto an inert fibrous support. The resulting conjugate pad and striped membrane are combined to construct the test strip. This test strip and a well to hold the swab specimen are mounted on opposite sides of a hinged, book-shaped test device (U.S. patent No. 91/214051). To perform the test (2 U.S. patents pending), a swab is dipped into the specimen, removed, and then inserted into the test device. Reagent A, a buffer solution, is added from a dropper bottle. The device is then closed, bringing the sample into contact with the test strip.

510(k) SUMMARY (Continued)

Pneumococcal antigen present in the sample reacts to bind anti-*S. pneumoniae* conjugate antibody. The resulting antigen-conjugate complexes are captured by immobilized anti-*S. pneumoniae* antibody, forming the Sample Line. Immobilized control antibody captures anti-species conjugate, forming the Control Line. There are no transferring steps, the sample is contained, and results are available within 15 minutes.

Intended Use:

The Binax NOW® *Streptococcus pneumoniae* Test is an *in vitro* rapid immunochromatographic (ICT) assay for the detection of *Streptococcus pneumoniae* (*S. pneumoniae*) antigen in the urine of patients with pneumonia and in the cerebral spinal fluid (CSF) of patients with meningitis. It is intended, in conjunction with culture and other methods, to aid in the presumptive diagnosis of both pneumococcal pneumonia and pneumococcal meningitis.

Technological Characteristics:

Both the Binax NOW® *Streptococcus pneumoniae* and the Wellcogen Bacterial Antigen Tests are simple rapid tests with a visual result interpretation. Both use a solid phase coated with polyclonal antibody to detect *S. pneumoniae* in human urine and CSF samples. However, the predicate device is a latex agglutination test employing antibody coated polystyrene beads that agglutinate in the presence of sufficient homologous antigen. The Binax NOW® *Streptococcus pneumoniae* Test is an immunochromatographic assay utilizing a colloidal gold conjugate and an antibody striped membrane to capture and visualize antigen.

Performance Summary:

The Binax NOW® *Streptococcus pneumoniae* Test is substantially equivalent to the predicate device, the Wellcogen Bacterial Antigen Test (K854852), for the detection of *S. pneumoniae* antigen in urine and CSF. The Binax NOW® *Streptococcus pneumoniae* Test has already been cleared for diganosis of pneumonia using a urine specimen (510(k) number K991762). No new data for the urine application is presented here. This

510(k) SUMMARY (Continued)

application focusses on performance of the Binax NOW® *Streptococcus pneumoniae* Test in CSF for the diagnosis of meningitis. The performance of the test in CSF was determined using freshly collected CSF specimens. Refer to attached **CSF PERFORMANCE CHARACTERISTICS.**

Signed J. Georges Nitis Ph.D Date 7/3/01

J. Georges Nitis, Ph.D., MBA
Director, Regulatory and Clinical Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Pamela Angell
Manager of Regulatory and Clinical Affairs
Program Planning and Implementation
Binax, Inc.
217 Read Street
Portland, ME 04103

NOV 3 0 2001

Re: k012521
Trade/Device Name: Binax Now® *Streptococcus pneumoniae* Test
Regulation Number: 21 CFR 862.3740
Regulation Name: Streptococcus spp. Serological reagents
Regulatory Class: Class I
Product Code: GTY
Dated: October 31, 2001
Received: November 8, 2001

Dear Ms. Angell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE ENCLOSURE

510(k) Number (if known): K012521

Device Name: Binax NOW® *Streptococcus pneumoniae* Test

Indications For Use:

The Binax NOW® *Streptococcus pneumoniae* Test is an *in vitro* rapid immunochromatographic (ICT) assay for the detection of *Streptococcus pneumoniae* (*S. pneumoniae*) antigen in the urine of patients with pneumonia and in the cerebral spinal fluid (CSF) of patients with meningitis. It is intended, in conjunction with culture and other methods, to aid in the presumptive diagnosis of both pneumococcal pneumonia and pneumococcal meningitis.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012521

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)